K080527

510(k) SUMMARY

OCT 31 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. *Name of Submitter, Contact Person and Date Summary Prepared:*

Julie Nunn
Managing Director
Trawax Pty Ltd
101 Darcey Road
Castle Hill NSW 2154
Australia
Phone: 61 419 256 218
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Summary Prepared On: 25 February 2008

2. *Device Name:*

Trade/Proprietary Name: TwinGuard® with Capnograph Accessory
Common/Usual Name: Endoscopic bite block and nasal oxygen cannula with capnograph accessory
Classification Name: Endoscopic bite block (Class I)
Nasal oxygen cannula (Class I)
Carbon dioxide analyzer (Class II)

3. *Legally Marketed Equivalent Device Name:*

The TwinGuard with Capnograph Accessory is substantially equivalence to the following devices:

Stantex Pty Ltd's Oxyguard endoscopic bite block, 510(k) K914978
Hudson Respiratory Care's nasal oxygen cannula, 510(k) K011125
Oridion Medical's Smart BiteBloc™, 510(k) K042665

510(k) SUMMARY

(Continued)

4. *Intended Use of the Device:*

TwinGuard®, a bite block with a nasal oxygen cannula, is used during endoscopy procedures to administer continuous oxygen to the nose and mouth. After endoscopy the bite block is removed, leaving the cannula in place during recovery, to continue delivering oxygen to the nose and mouth.. In addition, the TwinGuard® contains an optional accessory which collects samples of the patient's breathing at the nose and mouth to measure CO_2 with a capnograph during endoscopy procedures. It is intended for adult patients.

5. *Description of the Device:*

The TwinGuard® consists of an endoscopic bite block with an oxygen nasal cannula, which are Class I devices, exempt from premarket notification. The optional capnograph accessory, which enables continuous CO_2 monitoring during endoscopy procedures, is a Class II device.

6. *Device Comparison and Conclusion:*

The TwinGuard® with Capnograph Accessory has the same intended use as the predicate devices, and any technological differences with the predicate devices do not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Trawax Pty Limited
C/O Ms. Cindy Martin
Regulatory Affairs Associate II
29662 Avante
Laguna Niguel, California 92677

Re: K080527
Trade/Device Name: TwinGuard™ with Capnograph Accessory
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: I
Product Code: MNK, CCK
Dated: October 22, 2008
Received: October 23, 2008

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: TwinGuard™ with Capnograph Accessory

Indications For Use:

TwinGuard®, a nasal oxygen cannula and bite block, is used during endoscopy procedures to administer continuous oxygen to the nose and mouth. After endoscopy the bite block is removed, leaving the cannula in place during recovery, to continue delivering oxygen to the nose and mouth. In addition, the TwinGuard® contains an optional accessory which collects samples of the patient's breathing at the nose and mouth to measure CO_2 with a capnograph during endoscopy procedures. It is intended for adult patients.

Prescription Use __X__ OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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